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Filed : July 23, 2001

### REMARKS

In response to the Office Action, dated June 9, 2005, Applicant submits the foregoing amendments to claims 34, 35, and 43, cancels claims 40 and 42, and submits new claims 81-85. No new matter is added by the claim amendments or the new claims. Support for the amendments and new claims can be found at least at pages 123-134 of the originally submitted Specification and in Figures 20-26.

#### Objections to the Drawings

The Office Action indicates that the drawings are objected to under 37 CFR 1.83(a), because the drawings must show every feature of the invention specified in the claims, and the 'radiation inlet,' 'radiation outlet,' 'wave guide inlet', and 'wave guide outlet' must be shown or the feature(s) canceled from the claim(s).

The foregoing amendments to the claims removes any reference to a "radiation outlet", "wave guide inlet", and "wave guide outlet" so that objections to this specific language are moot.

After carefully analyzing the specification and the drawings, Applicant respectfully submits that the drawings provide support for an inlet where radiation is directed into a waveguide because FIG. 20B shows an entry point where radiation (e.g., light) is directed into the waveguide 20, even though the drawings do not expressly label this entry point as a "radiation inlet." Further support of an inlet for radiation to enter a waveguide is shown in FIG. 20A, which shows a top view of a single assay sector of an optical disc and illustrates a mirror configured to direct light into the waveguide, according to one embodiment. FIG. 20B shows a side view of the single assay sector of the optical disc shown in FIG. 20A, and expressly illustrates "Light" directed onto the "Mirror" and into a section of the assay substrate 20 that forms a waveguide (specification page 127 line 22 – page 128 line 8). FIG. 21A shows a side view of an assay site formed on a first exterior wall of the waveguide and specifically labels the substrate 20 as the "WAVEGUIDE." The corresponding description in the specification also supports that the drawings show a radiation inlet, as discussed below. Specification page 125 line 22 – page 128 line 2. Accordingly, Applicant respectfully submits every feature of the amended claims, including "an inlet where radiation is directed into said waveguide" are shown in the drawings, and requests the objections to the drawings be removed.

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#### Claim Objections

Claim 43 was objected to because it was improperly labeled as a withdrawn claim. Applicant thanks the Examiner for pointing out this typographical error, and the foregoing amendments have corrected claim 43 so that it is now labeled as a previously presented claim. Accordingly, Applicant respectfully requests the objection to claim 43 be withdrawn.

#### Objections to the Specification and Rejections under 35 U.S.C. § 112

The Office Action states that the specification is objected to as failing to provide proper antecedent basis for the claimed subject matter, and requested correction of the following: the terms 'radiant inlet', 'radiation outlet', 'wave guide inlet', and 'wave guide outlet' could not be found in the specification; Claim 43 is objected to because of the following informalities: claim 43 appears to have been improperly labeled as a withdrawn claim; claims 34-43 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; and Claim 34 is rejected because of the limitation 'said wave guide inlet' in the fifth line and 'said wave guide outlet' in the seventh line.

Claim 34 was rejected in the Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, on the basis the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Office Action indicates the Applicant fails to disclose the presence of radiation or wave guide inlets and radiation or wave guide outlets in the original disclosure.

The foregoing amendments to the claims remove any reference to a "radiation outlet", "wave guide inlet", and "wave guide outlet" so rejections to these specific terms are moot. Regarding the term "radiation inlet," Applicant respectfully submits the specification sufficiently discloses and teaches that the waveguide has some portion through which light enters the waveguide, termed an "inlet," in amended claim 34, e.g., "an inlet where radiation is directed

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into said waveguide..." (E.g., Specification page 123 line 8-11; FIG. 20B) as further discussed below.

Patents are required to "teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997). However, the U.S. Court of Appeals for the Federal Circuit has repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art. Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 664 (Fed. Cir. 1986); In re Howarth, 654 F.2d 103, 105 (CCPA 1981) ("An inventor need not, however, explain every detail since he is speaking to those skilled in the art."); In re Lange, 644 F.2d 856, 863 (CCPA 1981). The C.A.F.C. has also noted that "[n]ot every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be." In re Gay, 309 F.2d 769, 774 (CCPA 1962).

Applicant submits that the specification provides sufficient detail to provide antecedent basis that the waveguide has some portion through which light enters the waveguide, termed an "inlet" in claim 34. For example, the specification discloses the substrate is used as a waveguide

"[t]he continuous monitoring assay devices profit from the ability to adapt the assay device substrate to serve as an optical waveguide" (specification, page 123, lines 6-8),

and further describes that radiation (e.g., light) is directed into the substrate waveguide, clearly teaching a portion of the waveguide is configured as an inlet so that light can enter the waveguide:

"[i]ncident light is directed into the device substrate via a radially disposed mirror integrated into the assay device itself; upon application of incident light, an evanescent wave propagates through the device substrate through internal reflectance." Specification, page 123, lines 8-13, FIG. 20B.

The specification describes that radiation can be directed to enter the waveguide through alternative embodiments, again thereby requiring an entrance or inlet portion for the light to enter the waveguide:

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"[a]lthough a mirror is preferred for directing incident light into the optical waveguide when visible or near infrared (NIR) radiation is used, prisms or diffraction gratings will also find use, especially for NIR or longer wavelength light. FIG. 26 demonstrates one embodiment, in which uncollimated, but focused light, is first collimated into (nearly) parallel rays by a lens. The collimated beam is then directed by a prism into the waveguide." Specification page 124, lines 21-30 (emphasis added).

Accordingly, Applicant respectfully submits the specification shows inputting light into the waveguide and provides proper antecedent basis for a corresponding limitation of "an inlet where radiation is directed into said waveguide" as claimed in amended claim 34, and respectfully requests that the objection to the specification be removed.

#### Rejections under 35 U.S.C. § 102

Claims 34-35, 38-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Mian et al. (US 6,319,469).

With respect to claim 34, the Office Action asserts

Mian teaches a disk comprising sample inlet ports, fluid microchannels, reagent reservoirs, reaction chambers, detection chambers, and sample outlet ports (column 3, lines 35-42). Specific sites on the disk also comprise elements that allow fluid to be analyzed, including thermal sources, light sources, as well as detectors for these effectors (column 3, lines 50-57). Fluorescence is coupled back into a waveguide on the disk, thereby increasing the efficiency of detection. Mian et al also teach a radiation inlet and radiation outlet (fig. 16). In these embodiments, the optical component preceding the detector can include a dispersive element to permit spectral resolution. Fluorescence excitation can also be increased through multiple reflections from surfaces in the device whenever noise does not scale with path length in the same way as with signal (column 21, lines 49-57). Mian et al further teach that the sample chamber can be a planar waveguide, wherein the analyte interacts on the face of the waveguide and light absorbance is the result of the attenuated total internal reflection (i.e., the analyte reduces the intensity source light if the analyte is sequestered at the surface of the sample chamber, using for example, specific binding to a compound embedded or attached to the chamber surface (column 22, 8-35).

Applicant respectfully submits that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. See M.P.E.P. § 2131. Applicant respectfully submits that neither the Office Action's

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description of Mian nor any other disclosure in the Mian reference does not teach or suggest at least the limitations of amended claim 34:

*a plurality of spatially addressable assay sites located on said first exterior surface, each of said assay sites comprising one or more signal elements attached to said first exterior surface of said waveguide on the outside of said radiation transmissive body, wherein said signal elements being capable of reacting with an analyte to form analyte bound signal elements which are capable of reflecting radiation that escapes through said first exterior surface back through said first exterior surface and through said second exterior surface; and*

*a detector configured to detect the radiation escaping through said second exterior surface of said transmissive body at said plurality of assay sites to identify said analyte that has reacted with said signal elements to form said analyte bound signal elements. (emphasis added).*

Instead, Mian discloses the detection of "absorbance measurements can be used to detect any analyte that changes the intensity of transmitted light" as it propagates along an optical path, and describes an embodiment where light is transmitted through a "sample chamber on the disk [which] can constitute a cuvette" or a "planar waveguide." Mian col. 22, 8-36. Mian also discloses an "arrangement providing transverse illumination in the lateral dimension" where "light is directed laterally through the detection chamber. Light passes through the detection cell and is redirected by another 45° mirror onto a photosensitive detector." Mian col. 53, 18-28, FIG. 16. However, Mian does not teach or suggest "radiation ... escapes through said first exterior surface back through said first exterior surface and through said second exterior surface" and "a detector configured to detect the change in radiation escaping through said second exterior surface of said transmissive body at said plurality of assay sites" as required by claim 34.

Because Mian does not teach or suggest all the limitations of claim 34, Applicant respectfully asserts claim 34 is in condition for allowance. Accordingly, Applicant respectfully requests the above-stated rejection be removed from claim 34 and submits claim 34 for further examination.

Claims 35, 38-39, 41 and 43 depend either directly or indirectly from claim 34. Accordingly, Applicant respectfully asserts claims 35, 38-39, 41 and 43 are also in condition for allowance for at least the same reasons.

Rejections under 35 U.S.C. § 103

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Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al [US 6,319,469] in view of Rothschild et al [US 5,986,076]. Applicant traverses these rejections.

As stated above, Applicant respectfully submits that Mian does not disclose all the elements of claim 34. Rothschild does not cure the deficiencies of Mian, and also does not teach or disclose at least

*a plurality of spatially addressable assay sites located on said first exterior surface, each of said assay sites comprising one or more signal elements attached to said first exterior surface of said waveguide on the outside of said radiation transmissive body, wherein said signal elements being capable of reacting with an analyte to form analyte bound signal elements which are capable of reflecting radiation that escapes through said first exterior surface back through said first exterior surface and through said second exterior surface; and*

*a detector configured to detect the radiation escaping through said second exterior surface of said transmissive body at said plurality of assay sites to identify said analyte that has reacted with said signal elements to form said analyte bound signal elements. (emphasis added).*

Both the Mian and Rothschild, singly or in combination do not teach or disclose the limitations of claim 34. Accordingly, as claims 36 and 37 depend either directly or indirectly from claim 34, Applicant respectfully asserts claims 36 and 37 are also in condition for allowance and submits them for further examination.

### CONCLUSION

The applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims for patentability purposes pursuant to statutory sections 102, 103, and 112, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of these amendments and remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language. Furthermore, any new claims presented above are of course intended to avoid the prior art, but

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are not intended as replacements or substitutes of any cancelled claims. They are simply additional specific statements of inventive concepts described in the application as originally filed.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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